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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,324	08/22/2001	Joan W. Conaway	OMRF 1001	3570

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EXAMINER

NICKOL, GARY B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 05/07/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/914,324

Applicant(s)

CONAWAY ET AL.

Examiner

Gary B. Nickol Ph.D.

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1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

Claims 1-23 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1 and 7 drawn to the special technical feature of an isolated Ring box protein comprising SEQ ID NO:1.

Group 2, claim(s) 2-6, drawn to the special technical feature of an isolated nucleic acid molecule encoding a Ring box protein, expression vectors, host cells, and a method for producing a recombinant Ring box protein.

It is noted that the claims below (Claims 8-16) have been determined to include linking claims. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s) 8 and 12, drawn to the special technical feature of a ubiquitin ligase protein complex. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 3, claim(s) 8-16 drawn to the special technical feature of purified ubiquitin ligase protein complex which is SCF comprising:

ONE cullin protein as recited in Claim 13;

ONE substrate recognition protein as recited in Claim 14;

ONE linker protein as recited in Claim 15.

Applicant must elect a single SCF ubiquitin ligase protein, each of which is a distinct invention.

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Group 4, claim(s) 8-16 drawn to the special technical feature of purified ubiquitin ligase protein complex which is VHL comprising:

ONE cullin protein as recited in Claim 13;

ONE substrate recognition protein as recited in Claim 14;

ONE linker protein as recited in Claim 15.

Applicant must elect a single VHL ubiquitin ligase protein, each of which is a distinct invention.

Group 5, claim(s) 17-18, in part, drawn to the special technical feature of a method for screening for potential therapeutic agents that **interfer** with Rbx-1-dependent stimulation of ubiquitin or a ubiquitin-like protein comprising forming a complex in vitro, adding a test compound, and determining if the complex remain intact or is disrupted by the compound.

Group 6, claim(s) 17-18, in part, drawn to the special technical feature of a method for screening for potential therapeutic agents that **augment** Rbx-1-dependent stimulation of ubiquitin or a ubiquitin-like protein comprising forming a complex in vitro, adding a test compound, and determining if the complex remain intact or is disrupted by the compound.

Group 7, claim(s) 19, 23 drawn to the special technical feature of a method for diagnosing a predisposition of a patient to certain carcinomas comprising collecting a tissue or body fluid sample from a patient, analyzing said tissue or body fluid for a quantity of any Ring box protein; predicting the predisposition of the patient to certain carcinomas based upon the amount of Ring box protein in the tissue or body fluid.

Group 8, claim(s) 20, 23 in part, drawn to the special technical feature of a method for treating Ring box protein associated carcinomas comprising administering to a patient that has a carcinoma a therapeutically effective amount of a compound that enhances in-vivo the expression of the Rbx1 gene which enhances the in vivo expression of the Ring box protein.

Group 9, claim(s) 20, 23 in part, drawn to the special technical feature of a method for augmenting metabolically deficient systems in animals comprising administering to a patient diagnosed with a cellular deficiency a therapeutically effective amount of a compound that enhances in-vivo the expression of the Rbx1 gene which enhances the in vivo expression of the Ring box protein.

Group 10, claim(s) 21, 23 in part, drawn to the special technical feature of a method for treating Ring box protein associated carcinomas in animals comprising administering a therapeutically effective amount of any Ring box protein.

Group 11, claim(s) 21, 23 in part, drawn to the special technical feature of a method for augmenting metabolically deficient systems in animals comprising administering a therapeutically effective amount of any Ring box protein to a patient that has a Ring box protein cellular deficiency.

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Group 12, claim(s) 22-23 drawn to the special technical feature of a method for evaluating the effectiveness of a therapeutic treatment for Ring box associated carcinomas comprising collecting a tissue or body fluid sample from a patient having been subjected to a therapeutic treatment for such carcinoma, determining the amount of any Ring box protein, comparing the determined amount to a standard indicative of normal Ring box protein levels.

The inventions listed as Groups 1-12 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups 1-12 encompass different special technical features as identified in the groupings above. The inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because under unity of invention between different categories of inventions unity of invention will only be found to exist if specific combinations of inventions are present. Those combinations include:

- A) A product and a special process of manufacture of said product.
- B) A product and a process of use of said product.
- C) A product, a special process of manufacture of said product, and a process of use of said product.
- D) A process and an apparatus specially designed to carry out said process.
- E) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, and multiple methods of using said products, as claimed in the instant application. Hence, only one product and one process of use of said product relate to a single general inventive concept. Since multiple products and multiple methods with different special technical features are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d). Accordingly, Groups 1-12 are not so linked as to form a single general inventive concept and restriction is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
Art Unit 1642

GBN
May 5, 2003

